Real time detection and tracking of gauzes by RFID UWB Technique

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***Abstract*—The paper presents the implementation of the GUID (Gauzes UWB Identifier) system to control the path of gauzes and other medical instruments during surgical operations. The system allows tracking of these devices during the entire surgery, with particular reference to real-time localization of gauzes within the patient's body. A precise localization of gauzes, available to the surgeon, permits an easy removal of these devices, which are sometimes difficult to identify by visual perception. The final objectives are the improvement of the patient safety, of surgeon working procedures, and the reduction of stress conditions of the surgical staff. The GUID prototype is based on RFID Ultra Wide Band(UWB) technology and the experimental phases were carried out in laboratory using the tags both in air and in biological tissue. The results show the performance of a correct identification of the tags and the accuracy of the calculated position with respect to the real position of the tags.**

***Index Terms*—Tracking of gauzes, RFID UWB, Localization technique**

I. Introduction

Events related to the persistence of gauzes and medical instruments inside the body at the end of surgery operation are critical for the patient and have a considerable importance for the health care and for the financial-legal status of the clinical service providers, both public and private. The data relating to US safety in surgery highlight an incidence of this phenomenon of about 2,000 to 3,000 cases for year, that are responsible for further complications. In order to reduce the occurrence of this event the commonly used approach is to count one or more times the gauzes used during the surgical operation and to compare the result with the number of gauzes after the operation. The limits of this approach are mainly due to the difficult handling of the heavily contaminated material, even with the necessary equipment, and the difficult to ensure a correct count of the number of gauzes when the stress levels connected with the operation become very high. In the past, several techniques have been developed to overcame the problem but they have not meet the favor of the most medical staffs due to some constraints, usability features, such as the hard and large footprint, or low accuracy and reliability of the measure. An automatic and reliable system could help the medical staff to avoid retained gauzes inside the patient because it can considerably reduce the stress of the surgeon and staff at the end of operation and considerably reduce the expenses of the medical providers due to a nearly elimination of re-operation, health complications and legal refunds. The use of RFID tag on the gauzes [1],[2] is a cost-effective solution thank to the wide availability on the market. These methods use RFID passive tags on the gauzes but these solution always requires human intervention which can fail in emergencies and stress situation and they do not provide the position of the gauze. The proposed GUID system allows the localization of gauzes by using RFID based on UWB technology and it has been patented by University of Florence-Italy[1]. The UWB techniques have relative bandwidths larger than 20% or absolute bandwidths of more than 500 MHz. Positioning systems employing UWB radios provide very good accuracy due to the high time resolution (large bandwidth) of UWB signals. UWB systems have low power spectral density that allows them to coexist with other radio or electrical devices. A series of test were carried out to demonstrated the traceability of laparatomic gauzes inside biological tissues and in vivo tests using the GUID prototype. The in vivo test was carried out in a reproduce surgical room and during the experiment a surgical staff was present to utilize and evaluate the effectiveness of tags on gauzes by using them within the areas under an abdominal surgery. The paper shows the results in terms of position identification stability and the range of accuracy obtained.

II. Medical issues and current technologies used for the gauzes counting

In medical literature items that have been unintentionally left behind in patients following surgery are referred to as retained foreign bodies (RFB). Surgical sponges and gauzes account for the majority of incidents (2/3 of all retained foreign bodies), but needles, knife blades, and other surgical instruments are also incriminated. Technically, retained surgical sponge is known as gossypiboma or otherwise as textilomas. The word gossypiboma is bilingually derived from Gossypium (Latin) which means cotton and Boma (Swahili) that means

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the place of concealment. Gossipiboma is a very critical event because it can occurs in almost every kind of surgery where internal swabs are needed (like in cardiothoracic surgery, exploratory laparotomy, gynaecologic procedures, internal fixation of fractures and even after neurosurgical procedures) and it can induce medical complication that can lead, in some cases, even to the death of the patient.

The actual occurrences of gossypiboma are difficult to evaluate because nearly all cases are settled as discretely as possible by the surgical service provider. However, the most cited medical study on this subject [3] estimated that cases of retained sponges and gauzes occur in US between 1 out of 8,801 to 1 out of 18,760 cases in patient operations at non-specialty acute-care hospitals, corresponding to one case or more each year for a typical large hospital. The percentage becomes higher for emergency department (about three times the global value) or in countries with a reduced nurse training. The number of the events could be also very high, for example a survey on the Hawaiian health system found 4,675 cases with 72 deaths in 6 years [4]. The actual strategy used for the prevention of this event is mainly based in the manual counting of the medical items before the use on the patient and after their removal. There is not a law or a standard for the counting process: the law only states that items should not be negligently left inside patients. The only hints are provided by AORN [5] in the form of five general guidelines for the process, on this basis every institution has to develop its own policies and procedures for counting. Gawande et al. [3] estimanted that, given the 28.4 million inpatient operations performed in US in 1999, more than 1,500 cases of a retained foreign body occur annually in the United States and each event costs about $50,000 to the health care system. More recent data of 2003 related only to children surgical operation of Shah at al. [6] report the occurrence of Gossypiboma to 1 in 32,672 cases with an associated cost of $42,077 for each event. Considering that in the 2009 about 40 million of surgical operation have been carried out in mainland US, with the hypothesis that the gossypiboma rate evaluated by Gawande et al. is still the same, it is possible to evaluate the number of the event to about 2,150 cases per year. This means at least $110 million of excess cost for the US health care institutions. This cost is a under estimation of the real cost, because a large number of gossypiboma are not reported to the patient and/or care institution by the medical staff in order to avoid medico-legal trials. This cost consider only the medical expenses in order to solve the problem but not include the cost of the litigation that, in US, could be very high.

At the moment, if manual counting is not correct the health protocols plans to use RX to detect the opaque filament in gauze, this involves suturing the patient and the subsequent surgical operation to remove the reatined gauze. Different solutions have been developed to automate the counting operation performed by the operator for the incoming and outcoming gauzes [7],[8],[9],[10]. The use of RFID tag on the gauzes [1],[2] is a cost-effective solution thank to the wide availability on the market. The use of RFID passive tags on the gauzes always requires human intervention to read the tags which can fail in emergencies and stress situations and these systems do not provide the position of the gauze. To overcame the human failures, the detector for reading the RFID tags introduced in the gauzes is a gate through which it passed the patient on the operating table as suggested in [11]. This method is very impractical due to the gate footprint and the need to move the patient for the detection of gauzes. The reliability of the counting process is the key issue for the choice of the tag. The use of UWB RFID tags allows to count the tags not only when they are in the starting shelf or in the waste collecting bin at the end of the operation, but also to monitor the number of gauzes used in the surgical zone. Stretching this concept the UWB tag can be utilized not only for counting gauzes but also to localize the position of the tags during the whole operation and providing to the surgeon a powerful tool to find an used gauze inside the surgical zone. The use of RFID tags in the gauze involves the need for a sterilization process, a biocompatibility guarantee, full operational functionality of sponges with RFID embedded. Regarding the sterilization process, passive tags can support the thermal cycle (134 $^{\circ}C$ for 20 minutes) and active tags can be sterilized by using chemicals cycle with Ethylene Oxide [12], due to the presence of battery. The biocompatibility of the tag is not an issue, in fact there is no limitation in the use of biocompatible, thermal and chemical resistant plastic to entirely cover the tag body, such as HDPE or other commonly used materials for medical applications. In laparotomic surgery the size of gauzes is about 20 cm $\times$ 20 cm so that their functionality is not compromised if a miniaturized RFID is embedded with a size of about 2 cm. of diameter. Customized active RFID can reach this dimension. A safety aspect must be discussed: if a retained tag occurs this presents the same danger for a patients approximately as retained gauzes, bistouries, forceps an other medical devices. However the use of RFID tags must be a support to the actual health protocol to reduce these occurrences.

III. RFID BASED ON UWB TECHNOLOGY AND GUID SYSTEM

The use of Radio Frequency Identification (RFID) in hospitals and healthcare facilities is just beginning to be accepted. It can, for example, control the admitting, screening and treating processes, enhance communications between caregivers and support teams, and reduce medical errors [13] for example in the case of blood bags identification for transfusions and for tracking of drugs. Generally for these application the RFID system uses passive (or semipassive) tags that must be excited by a reader to transmit data. Passive tags typically operate at frequencies of 128 kHz, 13.6 MHz, 915 MHz, or 2.45 GHz, and have read ranges varying from a few centimeters to 10 meters [14],[15]. Active tags have their own power source, provided by on-board battery, and they operate at higher frequencies-commonly 455 MHz, 2.45 GHz, or 5.8 GHz, depending on the application's read range and memory requirements. Readers can communicate with active RFID tags up to 500 meters away [16]. Due to the limited reading range

and the need to manually pass the reader in proximity of the tag, passive tags are unsuited for the detection and tracking of gauzes during operation. The GUID system adopts active tags based on Ultra Wide Band technology because UWB offers unmatched performance in providing accurate localization. This is due to the use of short, nanosecond duration, pulses: Impulse Radio (IR) approach utilizing pulse position modulation (PPM) allows an accurate measure of the arrival time of the transmitted pulses. UWB systems have a good time-domain resolution and can allow centimeters resolution capability for localization and tracking applications. In addition, the extremely low duty cycle waveforms used for this application have the added advantage of extreme longevity of operation with small batteries. UWB systems have low power spectral density that allows them to coexist with other radio services and offers resistance to signal distortions caused by the reflections of the environment especially in indoor scenario. The prototype GUID system uses the UWB tags provided by Ubisense Ltd, a company registered in England and Wales at Companies House (website http://www.ubisense.net/en) which work at the UWB frequencies from 6 GHz to 8 GHz.

An integrated use of Angle of Arrival (AoA) and Time Difference of Arrival technology (TDoA) allows the Ubisense sensors to provide position with high accuracy and low processing time (refer to the Ubisense website for further details). The GUID System, by using the Ubisense sensors, provides the position of the gauzes inside the patient, monitoring in real time the path of gauze: in air, inside the body, and finally in the basket. The GUID system includes a camera in the operating room for image acquisition of the patient, and an image processing software for reconstruction of the body. The locations of the gauzes are shown by arrows superimposed on this reconstructed and scaled image, to provide a safe and easy guide for the surgeon to the identification of medical gauzes.

IV. Experimental results

The system has been tested in different operating situations. In the first set of experiments we evaluated the performance of the localization system in free space. The second set of experiments has been aimed to measure the degradation of the performance when the RFID tags are surrounded in biological tissue. Last, an in-vivo experiment has been performed to assess the difference between actual surgery condition and the raw biological tissue, The in vivo experiment was carried out in a fac-simile of an operating room, with typical electrical medical equipments, such as electrosurgical, laser, electrocardiographs, endoscopes, LED surgical lights and during the experiment a surgical staff was present to utilize and evaluate the effectiveness of RFID gauzes by using ina an abdominal surgery. In all cases, the experiments have been carried out using a rectangular cell, having the four antennas at its corners. The cell size is approximately 4m× 3m, in order to simulate the actual localization of the antennas around the patient. Antennas have been placed at a height of approximately 3m, as to not interact with the medical staff work. A schematic representation of the position of the cell, compared to the size of a surgical room, is reported in Figure 1.

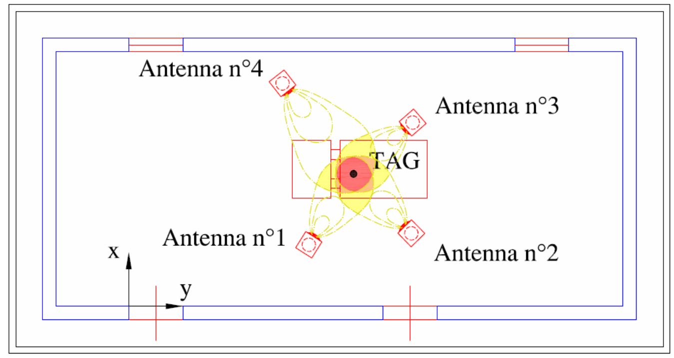

Fig. 1. Schematic representation of the location of the antennas in the measuring cell

A. Experiments in free space

Evaluation of the performances has been devoted to assess two different issues: the stability of the measure, and its accuracy. The stability of the measure has been evaluated by placing a series of tags scattered inside the cell region. Each tag was left in the same position for all the duration of the experiment. At the same time, a few more tags were moved around the cell to identify the possible interactions between different tags. Results indicate that, usually, the position measured by the system has a good stability. The observed position of each tag is, indeed, localized into a very small region of the cell (see Figure 2). The figure reports the position of the tags (colored dots) acquired during the experiment. The plot shows that two out of the three tags are localized with a very high stability, and the variability of the measure is of approximately ±5 centimeters. However, there are some positions, inside the cell, where the stability appears to decrease sensibly. For instance, the tag represented as blue dots has a stability along the x axis similar to green and red ones, but the uncertainty of the measure along the y axis is ±13cm. It should be observed, however, that the location of the blue tag is very close to the right edge of the measuring cell, and close to an obstacle. The decrease of the stability can indeed be related to multiple paths for the signal, and to an instability of the estimation algorithm along the line connecting two antennas. As concerns the precision of the measure, we evaluated the distance between the centroid of the sequence of measures for each tag, and compared it with the actual position of the tag in the room. Results, a sample of which is reported in Table I, indicate that the precision of the measure is in the range ±20cm, with an error increasing near the edges of the cell. A comparison with expected performance of the system suggests this is related to the reduced distance of the antennas with respect to the system specifications. This may increase the effect of uncertainties in the positioning of the antennas and in the calibration procedure. However, the repeatability of this error allows to compensate for it, reducing its effect during the clinical use of the system.

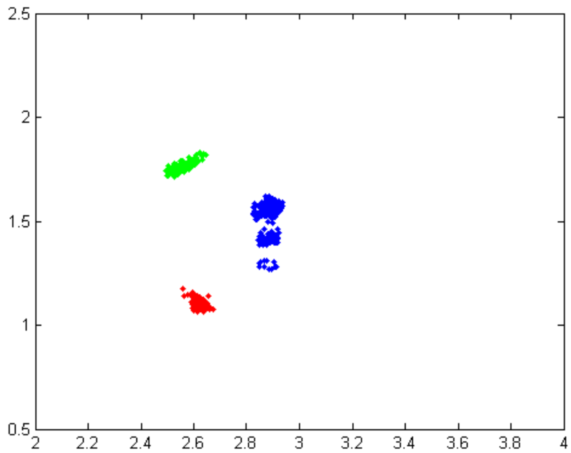

Fig. 2. Stability of tag localization: red and green, stable situation, blue, example of a critical situation. The reported measures are in meters.

TABLE I
SAMPLE RESULT ACQUIRED IN FREE SPACE

	The reported measures are in meters.	
Actual position	Measured position	Standard deviation
(3.67, 2.45)	(3.997,2.452)	(0.055,0.044)
(2.65, 2.45)	(2.671,2.460)	(0.025,0.016)
(1.18, 2.54)	(1.171,2.652)	(0.162,0.092)
(1.02, 3.03)	(1.418,3.002)	(0.066,0.134)
(2.36, 3.81)	(2.419,3.442)	(0.030,0.066)
(2.61,1.18)	(2.770,1.320)	(0.035,0.072)

B. Experiments in biological tissue

The second group of experiments concerns the possibility of correct detection of the RFID signal when the tag is included into a sample of biological tissue. The experiment has been carried out by inserting a RFID tag in a sample of raw meat. The tag was surrounded by a layer of meat of variable thickness (from 2 to 6 cm). The adopted configuration emulates the attenuation produced on the signal during a real surgical operation, allowing, at the same time, an extensive acquisition time and the possibility of an accurate monitoring of the position of the tag. Observed results indicate that the attenuation makes very difficult the localization of the tag, reducing both the frequency of localization (the triangulation algorithm fails to converge), and the precision of the localization itself. A numerical analysis of the results indicates a quite larger variance (as reported in table II). However, an accurate examination of the distribution of data, shown in Figure 3, suggests that the increase in the variance and the localization error are probably related to the presence of a minor number of acquisitions affected by a large error, while the majority of sample data is very close to the actual position of the tag (this effect if particularly evident in the tracking of the red tag). Figure 4 reports a sample histogram of the observed error, where it can be observed measures concentrated around the actual position. Using this information, we developed a simple algorithm which removes outliers (acquisition points which either report a large confidence interval, or are at a large distance from the average estimated position) is able to significantly improve the accuracy and precision of the estimate, as reported in table II. However, for real applications, a more sophisticate tracking algorithm is required, in order to further improve the accuracy and to take into account that the tag is moving inside the observed field during the surgical operation.

TABLE II
SAMPLE RESULTS ACQUIRED IN RAW MEAT.

	Position.The reported measures are in meters.		
Depth	Actual	Measured (raw)	Measured (post-process)
2 cm	2.60,1.75	$2.66\pm0.05, 1.60\pm0.17$	$2.64\pm0.04, 1.64\pm0.09$
4 cm	2.75,1.55	$2.83\pm0.28, 1.38\pm0.38$	$2.82\pm0.13, 1.52\pm0.11$
6 cm	2.50,1.54	$2.62\pm0.41, 1.27\pm0.61$	$2.60\pm0.15, 1.45\pm0.19$

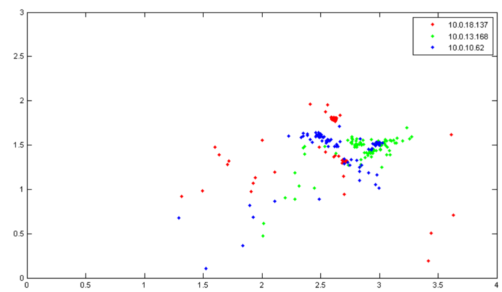

Fig. 3. Stability of tag localization: green and blue tags are embedded in raw meat, at different depth. The reported measures are in meters.

C. In vivo tests

In the last experiment, the actual surgical procedure has been tested on an alive specimen. Due to ethical reason, only one experiment has been performed to compare the results in the real situation with results during the simulations. The experiments have been carried on accordingly to all applicable local regulations and laws.The experiment is focused on a surgical operation on the abdomen, which is the most critical situation. During the experiment, a few gauzes labeled with a tag have been inserted in the subject, while the position of the tag was continuously monitored and recorded. In this case it was not possible to have an exact knowledge of the position of the tag, and we limited to evaluate the repeatability of the measure. However, a complete monitoring system can adopt time tracking strategies to improve the localization, as the gauze usually is not subjected to large movements while inside the subject body. Figure 5 shows the results of the measure. The subject body occupies the region corresponding to y=2m, with x ranging from 3.2m to 3.8m. The tag was moved inside the allowed x range. It can be observed how the dispersion of the measures is considerably larger than in the previous case. However, the average location of the localization is substantially correct.

V. CONCLUSIONS

The main goal of work is to prove that UWB signal can also be received if the tags are inside the patient body. During the

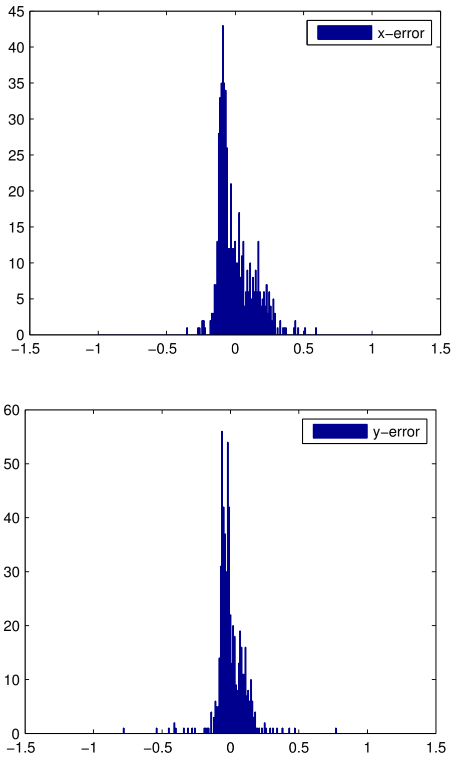

Fig. 4. Stability of tag localization: histograms of the localization error. The reported measures are in meters.

in vivo tests obtained on pigs undergoing surgical procedures, the GUID system has demonstrated fully compatibility with the medical instrumentation and electrical devices present in the specialized surgical room due to low interference of UWB technology. Obvious ethical reasons have required a limited number of in vivo tests. The position parameters are stable and the accuracy performance within ± 5 cm allows to identify the large laparotomic gauzes driving the surgeon in finding the missing gauze in the body area. The localization of the RFID tags is sufficient considering that at the moment this method can be only added to manual counting of the gauzes, the only solution worldwide used and allowed by actual regulations to search reatined gauzes. The proposed system automatically localizes the gauzes when they are out of the body patient; this allows to asses the absence of retained gauzes inside the body, which is the main font of stress for medical staff. However the accuracy may be improved by using a post processing algorithm and we are working on this at the moment. The system is currently being evaluated and redesigned for undergoing the necessary compatibility and reliability tests in order to obtain the certification by the Italian Health Authority, which is required to allow starting the experimentation directly on human subjects during surgery procedures.

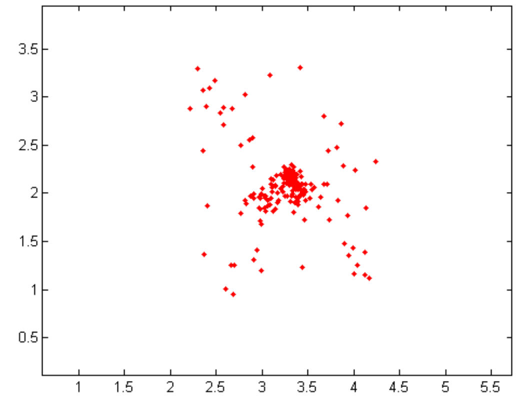

Fig. 5. Stability of tag localization: in vivo measurement.The reported measures are in meters.

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